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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,091

11/25/2003

Sebastiano Cavallaro

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EXAMINER

EMCH, GREGORY S

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/720,091	Applicant(s) CAVALLARO ET AL.	
	Examiner Gregory S. Emch	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 18-21 are drawn to a method of enhancing learning, memory and or attentive cognition in an individual, comprising administering an effective amount of FGF-18, classified in class 514, subclass 12, for example.
- II. Claims 11 and 12 are drawn to a method of determining the susceptibility of a subject to a condition, comprising removing and quantitating a CNS sample of FGF-18 mRNA, classified in class 435, subclass 6, for example.
- III. Claim 13 is drawn to a method for determining the pharmacological effect of a compound on the level of FGF-18 gene expression, comprising growing a culture(s) of neural cells; measuring the level of FGF-18 gene expression in the neural cells; contacting the compound with at least one of the cultures; and measuring the resultant level of FGF-18 expression, classified in class 435, subclass 7.2, for example.
- IV. Claims 14-17 are drawn to a method for identifying memory-related proteins, comprising providing naive, swimming control, and water-maze trained animals; extracting mRNA from said animals; determining differential gene expression levels by quantitating and comparing mRNA levels in naïve, control and trained animals so as to identify "memory

related genes"; and quantitating protein levels reflecting memory related genes for both control and target groups, classified in class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case the different inventions are directed to methods that are mutually exclusive, are not obvious variants and have a materially different design and mode of operation. The different methods are patentably distinct both physically and functionally, with different method steps and reagents. For example, Invention I requires administering an effective amount of FGF-18 to an individual, which is not required by any one of Inventions II-IV. Also, Invention II requires removing and quantitating a CNS sample of FGF-18 mRNA, which is not required by any one of Inventions I, III or IV. Invention III requires determining the pharmacological effect of a compound on the level of FGF-18 gene expression in neural cell cultures, which is not required by any one of Inventions I, II or IV. Further, Invention IV requires identifying memory-related proteins by extracting mRNA from naive, swimming control, and water-maze trained said animals and determining the differential gene expression levels,

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which is not required by any one of Inventions I-III. Therefore, a search and examination of all of these methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed Inventions I and II: clinical conditions.

- a. Impaired cognitive performance
- b. Learning deficit
- c. Cognition deficit
- d. Attention deficit
- e. Epilepsy
- f. Schizophrenia
- g. Alzheimer's disease
- h. Amnesiac syndrome

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-12 and 18-21 are generic.

If Applicants select either of Inventions I or II, one species from the clinical condition group must be chosen to be fully responsive.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement(s) be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and/or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicants traverse on the ground that the inventions or species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Gregory S. Emch, Art Unit 1649.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
07 July 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER